

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Call-in details: Dial **888-557-8511**; Enter Access Code **5222603#**

(Call 202-429-9260 if there are problems accessing the teleconference.)

Monday, July 27, 2009, 1:00 pm – 2:00 pm ET (call to start promptly at 1:00 pm ET)

Agenda (as of July 27, 2009 – subject to change)

- I. **Welcome and Introductions** 1:00 - 1:05 pm
 - Attendance taken via email (sent to Marcia Howard)
- II. **Next Standing Teleconference:** August 10, 2009 (unless cancelled)
- III. **Discussion Topics** 1:05 – 1:25 pm
 - A. NLM Pillbox Initiative

Tentative date for David Hale, Project Director to join teleconference is **August 24, 2009**.
 - B. Posting OTC information to DailyMed/FDA Facts page
- IV. **FDA Data Council Information** (*not all-inclusive*) 1:25 – 1:30 pm
 - A. The FDA Data Standards Council's website was updated Sunday, July 12, 2009, to include updated terminology lists:

UNII's (now over 10,000 UNII's publically available) -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>

Terminology XML Files (include updated UNII XML file) -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>

B. The FDA Data Standards Council's website was updated Thursday, July 16, 2009, to include new terms:

1. Business operation: API manufacture -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62527.htm>

2. Flavor: Marshmallow -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62541.htm>

C. The FDA Data Standards Council's website was updated Thursday, July 16, 2009, to included updated terminology lists:

UNII's -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>

Terminology XML Files (include updated UNII XML file) -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>

D. **Please only send SPL-related e-mails to the SPL e-mail account.** If you send a carbon copy of each of your SPL-related e-mails to lonnie.smith@fda.hhs.gov then Lonnie Smith (FDA) has to reach each message twice.

E. The FDA Data Standards Council's website was updated Friday, July 24, 2009, to included updated terminology lists:

UNII's -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>

Terminology XML Files (include updated UNII XML file) -

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>

F. Message received July 24, 2009, regarding common technical errors and other information.

Here is a list of common technical errors in SPL R4 documents received since the electronic drug establishment registration and drug listing pilot commenced on July 10, 2008, to June 1, 2009, when it became mandatory for the drug establishment registration and drug listing information to be provided in Structured Product Labeling format (unless a waiver is granted), to the present date.

1. **Missing folder** - Place each SPL document and any associated image file(s) in a folder and upload the folder containing the SPL and image files via the FDA Gateway's "OC" directory.
2. **Incorrect or missing file extension** - The file extension for SPL documents is ".xml" and the file extension for image files is ".jpg".
3. **Incorrect file format** - Winzip (zipped files) Excel, PDF, Word, and eCTD files are not acceptable formats for documents submitted for the purpose of electronically registering a drug establishment, submitting or requesting a NDC labeler code, or listing a drug product via the FDA OC Gateway. Only XML and JPEG (jpg) file formats are acceptable.
4. **Submitting more than one XML file per folder** - Only one SPL file should be included in each folder.
5. **Incorrect SPL file name** - Use the SPL document ID with the file extension ".xml"
6. **Not using the suffix element** - Utilize the suffix element for any additional qualifiers (e.g. dosage form, route of administration, etc...) for proprietary names.

Additional notes:

1. SPL Technical Q&A training sessions are held each Monday (except Federal holidays) from 11:30 a.m. - 12:00 p.m., (Eastern Time Zone): Audio Conference details: Telephone number: 1-866-775-9435 - Participant pass code: 2219058

1. Send SPL-related e-mails to the FDA SPL e-mail account: spl@fda.hhs.gov. Do not send SPL-related e-mails to both spl@fda.hhs.gov and lonnie.smith@fda.hhs.gov.

2. Test your SPL R4 documents via the Pragmatic Validator Lite tool to detect 90 - 95% of the technical errors which will be detected by FDA SPL R4 validation procedures:

3. The HL7 SPL Working Group has provided a hyperlink to the SPL Release Four Common Errors training slides: http://spl-work-group.wikispaces.com/file/view/common_errors_spl_r4_training.pdf.

4. The HL7 SPL Working Group's OTC sub team has provided a hyperlink to an OTC SPL document template: <http://spl-work-group.wikispaces.com/OTC>.

V. Open Discussion by Sub-team Members

1:30 – 1:45 pm

VI. Upcoming SPL Educational Forums/Information

1:45 – 1:50 pm

A. FDA SPL R4 Training Sessions – Please visit website for updated information regarding training courses.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155705.htm>

B. FDA weekly SPL R4 Q&A/Training session

June 8, 2009 – December 28, 2009

Mondays (except Federal holidays; no session held on June 22nd)

11:30 a.m. – 12:00 p.m. EST

Audio conference details:

Telephone number: 1-866-775-9435

Participant pass code: 2219058

- C. DIA SPL Workshop (August 11-12, 2009; The Westin Philadelphia, Philadelphia, PA)

<http://www.diahome.org/DIAHOME/Education/FindEducationalOffering.aspx?productID=20798&eventType=Meeting>

Early bird registration rate extended until **July 31, 2009** (\$190.00 savings). Please check with DIA or Westin Philadelphia regarding possible extension of room block.

- D. The SPL OTC template is available on the Wiki site (on the OTC sub-team page under "Training Materials." Visit <http://spl-work-group.wikispaces.com/> to access the file and for instructions for use.

Thanks to Lonnie Smith (FDA) and Priya Samuel (CHPA staff) for developing the template. Note the label was created for a fictitious OTC product and there are some placeholders on the template where companies should insert their specific information (e.g., associated establishments, application number).

- E. Others???

VII. Other

1:50 – 1:55 pm

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